

Remarks

Claims 1-2 and 6 are pending in the application. Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by a patent application by Kenna, EPO 0421485, ("Kenna '485"). Claims 2 and 6 stand rejected as obvious under 35 U.S.C. 103(a) over Kenna '485 and the knowledge of one skilled in the art.

Reference to the Declaration of Michael Mason under 37 C.F.R. 1.132 is made in the remarks below. This declaration was submitted with the response to the office action of March 24, 2005 for the subject case.

Applicant appreciates the opportunity for the telephonic interview held between Applicant's attorney, John Conway, and Examiners A. Reimers and E. Robert on March 13, 2006. The differences between the Kenna reference and claim 1 were discussed. Examiners A. Reimers and E. Robert pointed out that the protruding members of the Kenna reference may have more than 180 degrees of arc depending on how the angular measurement is taken. Attorney Conway indicated that adding a functional limitation to claim 1 concerning movement between the implant and the vertebra after the implant and vertebra might clarify the situation. No agreements were reached during the interview.

Claim 1 has been amended to more particularly define the claimed invention. Claim 1 now requires forming at least one keyway in each adjacent vertebra where the keyways are shaped to include a generally arcuate portion that encompasses more than one hundred and eighty degrees of curvature as measured from the center of curvature. Fig. 4, reproduced below, of the subject application shows an implant with protruding members for insertion in

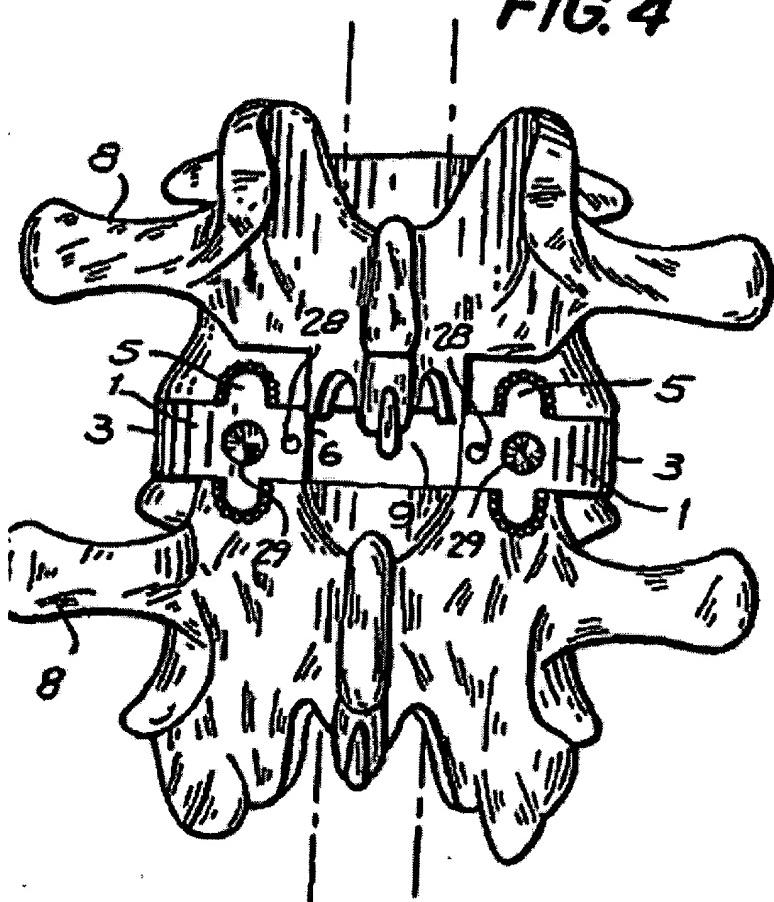
such keyways. Protruding members 74-77 clearly include arcuate portions that encompass more than one hundred and eighty degrees of curvature as measured from the center of curvature. Col. 2, lines 47-50 recite the step of forming corresponding keyways to accept the protruding members of the implant of fig. 4. Claim 1 has been further amended by adding the limitation “...such that movement between the implant and the first vertebra along any perpendicular to the longitudinal axis of the at least one keyway in the first vertebra is prevented.” Col. 2, lines 33-35 of the specification note that extension forces on the implant are neutralized by the shape of the protruding members. Thus, no new matter has been added.

Claim Rejections --- 35 U.S.C. §102(b)

Claim 1 stands rejected under 35 U.S.C. 102(b) as being anticipated by Kenna '485.

Kenna '485 teaches an apparatus for inserting a spinal implant. Kenna's implant is shown in fig. 4 of the '485 patent application:

**FIG. 4**



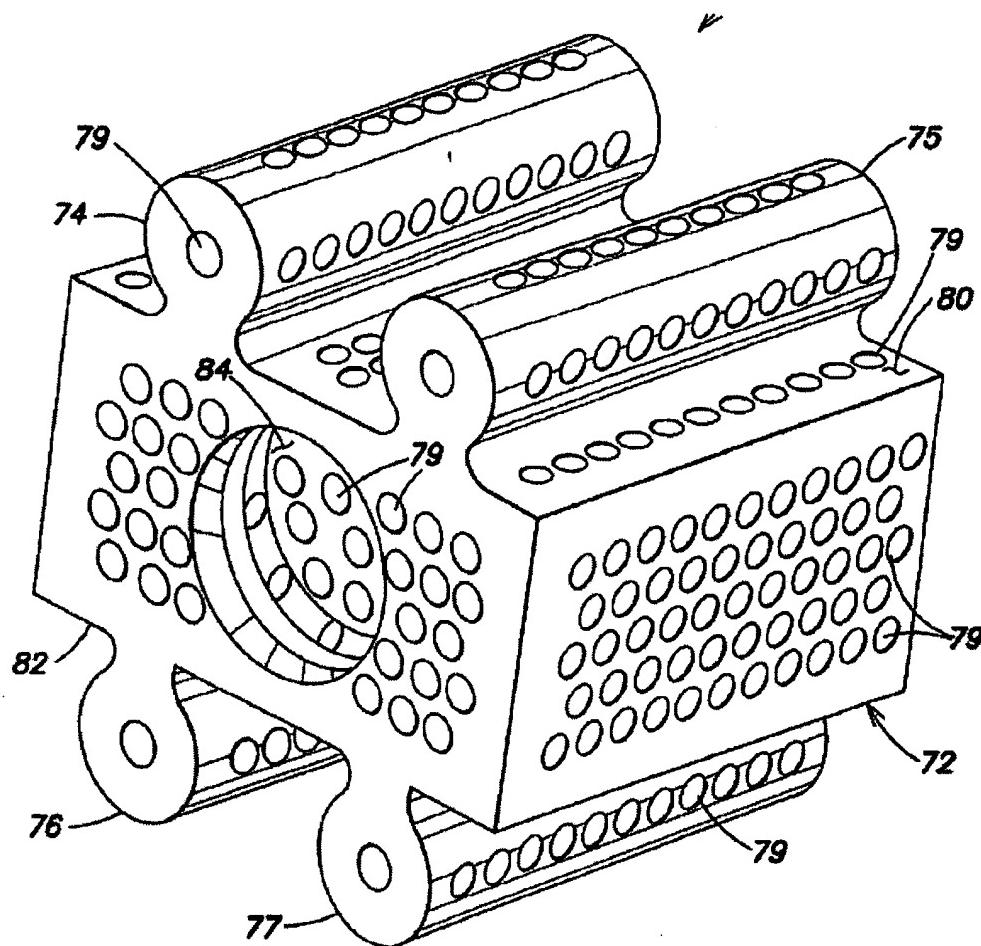
Kenna's protruding members **5**, as shown in fig. 4, have an arcuate portion with a limited angular measure. The keyways formed to receive these members are, likewise, arcuate in shape but limited in angular measure so that motion between the vertebra and the implant can still occur in a direction perpendicular to the longitudinal axis of each member **5**. That is, the vertebrae are not locked together by the implant members and keyways cut into the vertebrae, so that motion in a vertical direction is prevented, when the spine is vertical. Such motion would be perpendicular to the longitudinal axis of the protruding member 5 and its associated keyway.

Claim 1, as amended, requires (in part):

...

- b) forming at least one keyway in the first vertebra corresponding to each of the at least one protruding members on the first surface, and at least one keyway in the second vertebra corresponding to each of the at least one protruding members on the second surface, wherein each keyway is characterized by a keyway longitudinal axis and has a profile perpendicular to the keyway's longitudinal axis including a generally arcuate portion that encompasses more than one hundred and eighty degrees of curvature as measured from the center of curvature,; and
- c) inserting the implant between the first vertebra and the second vertebra in a manner so that each protruding member slides into the corresponding keyway;  
such that movement between the implant and the first vertebra along any perpendicular to the longitudinal axis of the at least one keyway in the first vertebra is prevented. “

In contrast, protruding members for embodiments of the present invention encompass more than 180 degrees in curvature as measured from the center of curvature as shown in fig. 4 of the subject application:



**FIG. 4**

The additional arcuate angular measure beyond 180 degrees allows the keyway to engage with the protruding member so that the only motion possible is parallel to the longitudinal axes of the protruding member and the keyway. This retaining action by the keyway on the protruding member assists in fusing the vertebrae: the vertebrae are prevented from separating in a vertical

direction. Kenna's implant, since it's arcuate measure is no more than 180 degrees, provides no similar action.

Since Kenna '485 does not teach forming keyways in the adjacent vertebrae that correspond to protruding members with an arcuate shape encompassing more than 180 degrees of curvature as measured from the center of curvature, Kenna '485 cannot anticipate claim 1. Further, since Kenna's keyways allow movement of the implant in a direction perpendicular to the longitudinal axis of the keyway – at least in the direction that is normal to the surface of the implant -- Kenna's method does not meet the limitation:

“...such that movement between the implant and the first vertebra along any perpendicular to the longitudinal axis of the at least one keyway in the first vertebra is prevented” of claim 1, as amended.

Thus, Kenna '485 cannot anticipate claim 1, as amended.

Claim Rejections --- 35 U.S.C. §103(a)

Claims 2 and 6 stand rejected as obvious under 35 U.S.C. 103(a) over Kenna '485 and the knowledge of one skilled in the art.

These rejections for obviousness rely on Kenna '485 for teaching the same limitations of the claims that are contained in claim 1. Thus, as for claim 1, since Kenna '485 does not teach, disclose or suggest the limitations of claim 1 cited above, claim 2, which includes these limitations, cannot be obvious over Kenna '485 in view of the knowledge of one skilled in the art.

Further, as regards both claims 2 and 6, providing two protruding members on each body surface of the implant and cutting two corresponding

keyways in the vertebrae is not simply a duplication of design elements. As stated in paragraphs 6 and 7 of the Declaration of Dr. Mason, submitted under 37 C.F.R. § 1.132 with a previous response in this application, such multiple members and keyways take advantage of characteristics of bone to achieve better mechanical fixation of the implant with the vertebrae. Cortical bone, which is at the periphery of a bone, is denser and better able to support a mechanically rigid coupling to the implant. The multiple members of the implant, rather than a single member, lead to implantation in this cortical bone, and a superior result, over prior art methods. Thus, claims 2 and 6 cannot be obvious in light of the Kenna reference and matters of simple design choice.

For the reasons set forth above, it is submitted that all pending claims are now in condition for allowance. Reconsideration of all pending claims and a notice of allowance are therefore requested. If any additional fees are required for the timely consideration of this application, please charge deposit account number 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Respectfully submitted,



John L. Conway  
Registration No. 48,241  
Attorney for Applicant

Bromberg & Sunstein LLP  
125 Summer Street  
Boston, MA 02110-1618  
(617) 443-9292

02731/00103 472288.1